during treatment and for 4 days following the last treatment. Milk that has been taken during treatment and for 24 hours (two milkings) after the last treatment must not be used for food. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[51 FR 44450, Dec. 10, 1986, as amended at 61 FR 29480, June 11, 1996; 62 FR 4164, Jan. 29, 1997]

§ 522.2640 Tylosin injectable dosage forms.

§ 522.2640a Tylosin injection.

(a) *Specifications.* Each milliliter of sterile solution of 50 percent propylene glycol with 4 percent benzyl alcohol contains 50 to 200 milligrams of tylosin activity (as tylosin base). Tylosin conforms to the appropriate antibiotic standard. Tylosin contains at least 95 percent tylosin as a combination of tylosin A, tylosin B, tylosin C, and tylosin D of which at least 80 percent is tylosin A as determined by a method entitled ''Determination of Factor Content in Tylosin by High Performance Liquid Chromatography,'' which is incorporated by reference. Copies are available from the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857, or available for inspection at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC 20001.

(b) *Sponsors.* (1) See No. 000986 in § 510.600(c) of this chapter for use in paragraphs (e)(1), (2), and (3) of this section.

(2) See No. 000010 in § 510.600(c) of this chapter for use as in paragraphs (e)(1) and (2) of this section.

(c) *NAS/NRC status.* These conditions of use are NAS/NRC reviewed and found effective. NADA's for these uses need not include effectiveness data as specified by § 514.111 of this chapter but may require bioequivalency and safety information.

(d) *Related tolerances.* See § 556.740 of this chapter.

(e) *Conditions of use*—(1) *Beef cattle and nonlactating dairy cattle*—(i) *Amount.* 8 milligrams per pound of body weight once daily.

(ii) *Indications for use.* Treatment of bovine respiratory complex (shipping fever, pneumonia) usually associated with *Pasteurella multocida* and *Corynebacterium pyogenes;* foot rot (necrotic pododermatitis) and calf diphtheria caused by *Fusobacterium necrophorum* and metritis caused by *Corynebacterium pyogenes.*

(iii) *Limitations.* Administer intramuscularly for not more than 5 consecutive days. Continue treatment 24 hours after symptoms disappear. Do not inject more than 10 milliliters per site. Do not use in lactating dairy cattle. Use a 50-milligram-per-milliliter solution for calves weighing less than 200 pounds. Do not administer within 21 days of slaughter.

(2) *Swine*—(i) *Amount.* 4 milligrams per pound of body weight twice daily.

(ii) *Indications for use.* Treatment of swine arthritis caused by *Mycoplasma hyosynoviae;* swine pneumonia caused by *Pasteurella* spp.; swine erysipelas caused by *Erysipelothrix rhusiopathiae;* swine dysentery associated with *Treponema hyodysenteriae* when followed by appropriate medication in the drinking water and/or feed.

(iii) *Limitations.* Administer intramuscularly for not more than 3 consecutive days. Continue treatment 24 hours after symptoms disappear. Do not inject more than 5 milliliters per site. Do not administer within 14 days of slaughter. If tylosin medicated drinking water is used as followup treatment for swine dysentery, the animal should thereafter receive feed containing 40 to 100 grams of tylosin per ton for 2 weeks to assure depletion of tissue residues.

(3) *Dogs and cats*—(i) *Amount.* 3 to 5 milligrams per pound of body weight at 12- to 24-hour intervals.

(ii) *Indications for use*—(*a*) *Dogs.* Treatment of upper respiratory infections such as bronchitis, tracheobronchitis, tracheitis, laryngitis, tonsillitis, and pneumonia caused by *Staphylococci* spp., hemolytic *Streptococci* spp., and *Pasteurella multocida.*

(*b*) *Cats.* Treatment of upper respiratory infections when caused by *Staphylococci* spp. and hemolytic *Streptococci* spp. and for feline pneumonitis when caused by tylosin susceptible organisms.

(iii) *Limitations.* For intramuscular use only. If there is no response to therapy in 5 days, diagnosis and treatment should be reassessed. Use a 50-milligram-per-milliliter solution only. Dogs and cats receiving a dose of less than 50 milligrams (1 milliliter) should be dosed with a tuberculin syringe. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[46 FR 48643, Oct. 2, 1981, as amended at 47 FR 9398, Mar. 5, 1982; 50 FR 49841, Dec. 5, 1985; 50 FR 50292, Dec. 10, 1985; 53 FR 40728, Oct. 18, 1988; 59 FR 14365, Mar. 28, 1994; 62 FR 35077, June 30, 1997]

§ 522.2662 Xylazine hydrochloride injection.

(a) *Specifications.* Xylazine hydrochloride injection is a sterile aqueous solution containing xylazine hydrochloride equivalent to 100 milligrams of xylazine in each milliliter of solution when intended for use in horses, wild deer, and elk, and 20 milligrams of xylazine per milliliter of solution when intended for use in dogs and cats.

(b) *Sponsor.* See 000856 in § 510.600(c) of this chapter for use in horses, wild deer, and elk. See 000859 and 061651 in § 510.600(c) of this chapter for use in horses, wild deer, elk, dogs, and cats. See 061690 in § 510.600(c) of this chapter for use in horses, wild deer, elk, dogs, and cats. See 000010 in § 510.600(c) of this chapter for use in horses only.

(c) *Conditions of use.* (1) The drug is used in horses, wild deer, elk, dogs, and cats to produce sedation, as an analgesic, and a preanesthetic to local anesthesia. It may also be used in horses, dogs, and cats as a preanesthetic to general anesthesia.

(2) It is administered as follows:

(i) To horses from a solution containing 100 milligrams of xylazine per milliliter, intravenously at 0.5 milligram per pound of body weight, or intramuscularly at 1.0 milligram per pound of body weight.

(ii) To dogs and cats from a solution containing 20 milligrams of xylazine per milliliter; intravenously at 0.5 milligram per pound of body weight or intramuscularly or subcutaneously at 1.0 milligram per pound of body weight. In dogs over 50 pounds, a dosage of 0.5 mg. per pound administered intramuscularly may provide sufficient sedation and/or analgesia for most procedures.

(iii) To wild deer and elk from a solution containing 100 milligrams of xylazine (as xylazine hydrochloride) per milliliter, intramuscularly, by hand syringe or syringe dart, in the heavy muscles of the croup or shoulder as follows:

(*a*) Fallow deer, 2 to 4 milligrams per pound.

(*b*) Mule deer, sika deer, and whitedeer, 1 to 2 milligrams per pound.

(*c*) Elk, 0.25 to 0.5 milligram per pound.

(3) Not to be administered to food-producing animals.

(4) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[40 FR 13858, Mar. 27, 1975, as amended at 41 FR 24884, June 21, 1976; 41 FR 28265, July 9, 1976; 53 FR 4848, Feb. 18, 1988; 53 FR 23608, June 23, 1988; 53 FR 40728, Oct. 18, 1988; 55 FR 18724, May 4, 1990; 55 FR 32616, Aug. 10, 1990; 59 FR 14367, Mar. 28, 1994; 60 FR 33110, June 27, 1995; 60 FR 35122 and 35123, July 6, 1995; 61 FR 46548, Sept. 4, 1996; 62 FR 35077, June 30, 1997]

§ 522.2670 Yohimbine injectable.

(a) *Specifications.* Each milliliter of sterile aqueous solution contains either 2 or 5 milligrams of yohimbine (as hydrochloride).

(b) *Sponsor.* See 061690 in § 510.600(c) of this chapter for use of 2 milligrams per milliliter solution in dogs.

(1) *Amount.* 0.05 milligram per pound (0.11 milligram per kilogram) of body weight.

(2) *Indications for use.* To reverse the effects of xylazine in dogs.

(3) *Limitations.* For intravenous use in dogs only. Not for use in food-producing animals. Safety of use in pregnant dogs or in dogs intended for breeding has not been established. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(c) *Sponsor.* See 053923 in § 510.600(c) of this chapter for use of 5 milligrams per milliliter solution in deer and elk.